

PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the Application of

Tsuyoshi TADA et al.

Application No.: 10/579,297

Filed: June 6, 2006

Docket No.: 128045

For: HYDROCEPHALUS TREATMENT

INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

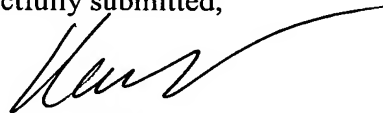
Sir:

Pursuant to 37 CFR §1.56, the attention of the Patent and Trademark Office is hereby directed to the reference(s) listed on the attached PTO-1449. Unless otherwise indicated herein, one copy of each reference is attached. It is respectfully requested that the information be expressly considered during the prosecution of this application, and that the reference(s) be made of record therein and appear among the "References Cited" on any patent to issue therefrom.

- ☒ 1. This Information Disclosure Statement is being filed (a) within three months of the U.S. filing date of this non-CPA application, OR (b) before the mailing date of a first Office Action on the merits in the present application. No certification or fee is required.
- ☒ 2. One or more reference cited herein was cited in the International Search Report. An English language version of the International Search Report is attached for the Examiner's information. See References 1, 2, 46, 47 and 49 - 52.
- ☒ 3. In accordance with 37 CFR §1.98(a)(2)(ii), copies of any U.S. patents and patent application publications are not attached.
- ☒ 2. An English language Abstract of one or more non-English language reference is attached hereto. See Reference 2.

- ☒ 3. A computer-generated English language translation of one or more Japanese Patent Publication cited herein has been obtained from the website of the Japanese Patent Office ([<http://www.jpo.go.jp>]), and is attached, but has not been reviewed for accuracy. See Reference 2.

Respectfully submitted,



William P. Berridge  
Registration No. 30,024

Randi B. Isaacs  
Registration No. 56,046

WPB:RBI/kam

Date: November 22, 2006

**OLIFF & BERRIDGE, PLC**  
**P.O. Box 19928**  
**Alexandria, Virginia 22320**  
**Telephone: (703) 836-6400**

**DEPOSIT ACCOUNT USE  
AUTHORIZATION**

Please grant any extension  
necessary for entry;  
Charge any fee due to our  
Deposit Account No. 15-0461

Form PTO-1449 (REV. 1/06)		US Dept. of Commerce PATENT & TRADEMARK OFFICE		ATTY DOCKET NO. 128045		APPLICATION NO. 10/579,297	
INFORMATION DISCLOSURE STATEMENT  (Use several sheets if necessary)				APPLICANT Tsuyoshi TADA et al.			
				FILING DATE May 15, 2006			
U.S. PATENT DOCUMENTS							
Examiner Initials	Cite No.	Document Number	Date	Name			
	1	5,840,311	11/24/1998	NAKAMURA et al.			
FOREIGN PATENT DOCUMENTS							
Examiner Initials	Cite No.	Document Number	Date	Country	With English Abstract	With English Translation	
	2	JP A 7-300426	11/14/1995	JAPAN	X	X	
OTHER DOCUMENTS							
Examiner Initials	Cite No.	(Including Author, Title, Date, Pertinent Pages, etc.)					
	3	Di Rocco et al., "Anatomo-Clinical Correlations in Normotensive Hydrocephalus," Journal of the Neurological Sciences, Vol. 33, pp. 437-452, 1977.					
	4	Yasargil et al., "Hydrocephalus following spontaneous subarachnoid hemorrhage, Clinical features and treatment," J. Neurosurg., Vol. 39, pp. 474-479, October 1973.					
	5	Almuneef et al., "Childhood Bacterial Meningitis in Saudi Arabia," Journal of Infection, Vol. 36, pp. 157-160, 1998.					
	6	Daoud et al., "Indications and Benefits of Computed Tomography in Childhood Bacterial Meningitis," Journal of Tropical Pediatrics, Vol. 44, pp. 167-169, June 1998.					
	7	Gomes et al., "Prognosis of Bacterial Meningitis in Children," Arq Neuropsiquiatr, Vol. 54, No. 3, pp. 407-411, 1996.					
	8	Grimwood et al., "Adverse Outcomes of Bacterial Meningitis in School-Age Survivors," Pediatrics, Vol. 95, No. 5, pp. 646-656, May 1995.					
	9	Youmans, J.R., Chapter 36; "Hydrocephalus in Childhood," Neurological Surgery, Fourth Edition, Vol. 2, W.B. Saunders Company, Philadelphia, pp. 890-926, 1996.					
	10	Graff-Radford et al., "Factors Associated With Hydrocephalus After Subarachnoid Hemorrhage, A Report of the Cooperative Aneurysm Study," Arch Neurol, Vol. 46, pp. 744-752, July 1989.					
	11	Pfister et al., "Spectrum of Complications During Bacterial Meningitis in Adults, Results of a Prospective Clinical Study," Arch. Neurol, Vol. 50, No. 6, pp. 575-581, June 1993.					
EXAMINER					DATE CONSIDERED		
Examiner: Initial if citation considered, whether or not citation is in conformance with M.P.E.P. 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.							

Date: November 22, 2006

Form PTO-1449 (REV. 1/06)		US Dept. of Commerce PATENT & TRADEMARK OFFICE		ATTY DOCKET NO. 128045		APPLICATION NO. 10/579,297	
INFORMATION DISCLOSURE STATEMENT  (Use several sheets if necessary)				APPLICANTS Tsuyoshi TADA et al.			
				FILING DATE May 15, 2006			
U.S. PATENT DOCUMENTS							
Examiner Initials	Cite No.	Document Number	Date	Name			
FOREIGN PATENT DOCUMENTS							
Examiner Initials	Cite No.	Document Number	Date	Country	With English Abstract	With English Translation	
OTHER DOCUMENTS							
Examiner Initials	Cite No.	(Including Author, Title, Date, Pertinent Pages, etc.)					
	12	Lobato et al., 'Hydrocephalus in cerebral cysticercosis, Pathogenic and therapeutic considerations," J. Neurosurg., Vol. 55,					
		pp. 786-793, November 1981.					
	13	Torvik et al., "Transitory Block of the Arachnoid Granulations Following Subarachnoid Haemorrhage: A Postmortem Study,"					
		Acta Neurochirurgica, Vol. 41, pp. 137-146, 1978.					
	14	Akai et al., "Normal Pressure Hydrocephalus, Neuropathological Study," Acta Pathol. Jpn., Vol. 37, No. 1, pp. 97-110,					
		1987.					
	15	Massicotte et al., "Human arachnoid villi response to subarachnoid hemorrhage: possible relationship to chronic hydrocephalus,"					
		J. Neurosurg., Vol. 91, pp. 80-84, July 1999.					
	16	Motohashi et al., 'Subarachnoid Haemorrhage Induced Proliferation of Leptomeningeal Cells and Deposition of Extracellular					
		Matrices in the Arachnoid Granulations and Subarachnoid Space," Acta Neurochir, Vol. 136, pp. 88-91, 1995.					
	17	Kang et al., "Long-term follow-up of shunting therapy," Child's Nerv Syst, Vol. 15, pp. 711-717, 1999.					
	18	Sgouros et al., "Long-Term Complications of Hydrocephalus," Pediatr Neurosurg, Vol. 23, pp. 127-132, 1995.					
	19	Del Bigio, "Epidemiology and Direct Economic Impact of Hydrocephalus: A Community Based Study," Can J. Neurol. Sci.,					
		Vol. 25, pp. 123-126, 1998.					
	20	Nakamura et al., "Molecular cloning and expression of human hepatocyte growth factor," Nature, Vol. 342, pp. 440-443,					
		November 23, 1989.					
EXAMINER					DATE CONSIDERED		
Examiner: Initial if citation considered, whether or not citation is in conformance with M.P.E.P. 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.							

Date: November 22, 2006

Form PTO-1449 (REV. 1/06)		US Dept. of Commerce PATENT & TRADEMARK OFFICE		ATTY DOCKET NO. 128045		APPLICATION NO. 10/579,297	
INFORMATION DISCLOSURE STATEMENT  (Use several sheets if necessary)				APPLICANTS Tsuyoshi TADA et al.			
				FILING DATE May 15, 2006			
U.S. PATENT DOCUMENTS							
Examiner Initials	Cite No.	Document Number	Date	Name			
FOREIGN PATENT DOCUMENTS							
Examiner Initials	Cite No.	Document Number	Date	Country	With English Abstract	With English Translation	
OTHER DOCUMENTS							
Examiner Initials	Cite No.	(Including Author, Title, Date, Pertinent Pages, etc.)					
	21	Miyazawa et al., "Molecular Cloning and Sequence Analysis of the cDNA for a Human Serine Protease Responsible for Activation of Hepatocyte Growth Factor," The Journal of Biological Chemistry, Vol. 268, No. 14, pp. 10024-10028, 1993.					
	22	Dohi et al., "Hepatocyte Growth Factor Attenuates Collagen Accumulation in a Murine Model of Pulmonary Fibrosis," Am J Respir Crit Care Med, Vol. 162, pp. 2302-2307, 2000.					
	23	Matsuda et al., "Hepatocyte Growth Factor Suppresses the Onset of Liver Cirrhosis and Abrogates Lethal Hepatic Dysfunction in Rats," J. Biochem, Vol. 118, No. 3, pp. 643-649, 1995.					
	24	Fujimoto, "Hepatology: Microcirculation and Pathogenesis of Alcoholic Liver Injury, Gene therapy for liver cirrhosis," Journal of Gastroenterology and Hepatology, Vol. 15 (Suppl.), pp. D33-D36, 2000.					
	25	Vargas et al., "Hepatocyte growth factor in renal failure: Promise and reality," Kidney International, Vol. 57, pp. 1426-1436, 2000.					
	26	Rosen et al., "Scatter Factor and the <i>c-Met</i> Receptor: A Paradigm for Mesenchymal/Epithelial Interaction," The Journal of Cell Biology, Vol. 127, Number 6, Part 2, pp. 1783-1787, December 1994.					
	27	Brinkmann et al., "Hepatocyte Growth Factor/Scatter Factor Induces a Variety of Tissue-Specific Morphogenic Programs In Epithelial Cells," The Journal of Cell Biology, Vol. 131, Number 6, Part 1, pp. 1573-1586, December 1995.					
	28	Ohmichi et al., "Hepatocyte growth factor (HGF) acts as a mesenchyme-derived morphogenic factor during fetal lung development," Development, Vol. 125, pp. 1315-1324, 1998.					
	29	Matsumoto et al., "Hepatocyte growth factor in renal regeneration, renal disease and potential therapeutics," Current Opinion in Nephrology and Hypertension, Vol. 9, pp. 395-402, 2000.					
EXAMINER					DATE CONSIDERED		
Examiner: Initial if citation considered, whether or not citation is in conformance with M.P.E.P. 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.							

Date: November 22, 2006

Form PTO-1449 (REV. 1/06)		US Dept. of Commerce PATENT & TRADEMARK OFFICE		ATTY DOCKET NO. 128045		APPLICATION NO. 10/579,297	
INFORMATION DISCLOSURE STATEMENT  (Use several sheets if necessary)				APPLICANTS Tsuyoshi TADA et al.  FILING DATE May 15, 2006			
U.S. PATENT DOCUMENTS							
Examiner Initials	Cite No.	Document Number	Date	Name			
FOREIGN PATENT DOCUMENTS							
Examiner Initials	Cite No.	Document Number	Date	Country	With English Abstract	With English Translation	
OTHER DOCUMENTS							
Examiner Initials	Cite No.	(Including Author, Title, Date, Pertinent Pages, etc.)					
	30	Flood et al., "Transforming Growth Factor- $\beta$ 1 in the Cerebrospinal Fluid of Patients with Subarachnoid Hemorrhage: Titers Derived From Exogenous and Endogenous Sources," Journal of Cerebral Blood Flow and Metabolism, Vol. 21, pp. 157-162, 2001.					
	31	Takizawa et al., "Inflammatory cytokine cascade released by leukocytes in cerebrospinal fluid after subarachnoid hemorrhage," Neurological Research, Vol. 23, pp. 724-730, October 2001.					
	32	Ossege et al., "Expression of tumor necrosis factor- $\alpha$ and transforming growth factor- $\beta$ 1 in cerebrospinal fluid cells in meningitis," Journal of the Neurological Sciences, Vol. 144, pp. 1-13, 1996.					
	33	Hunag et al., "Level of transforming growth factor beta 1 is elevated in cerebrospinal fluid of children with acute bacterial meningitis," J. Neurol, Vol. 244, pp. 634-638, 1997.					
	34	Galbreath et al., "Overexpression of TGF- $\beta$ 1 in the Central Nervous System of Transgenic Mice Results in Hydrocephalus," Journal of Neuropathology and Experimental Neurology, Vol. 54, No. 3, pp. 339-349, May 1995.					
	35	Wyss-Coray et al., "Increased Central Nervous System Production of Extracellular Matrix Components and Development of Hydrocephalus in Transgenic Mice Overexpressing Transforming Growth Factor- $\beta$ 1," American Journal of Pathology, Vol. 147, No. 1, pp. 53-67, July 1995.					
	36	Cohen et al., "Characterization of a model of hydrocephalus in transgenic mice," J. Neurosurg., Vol. 91, pp. 978-988, December 1999.					
	37	Stoddart, Jr. et al., "Transgenic Mice with a Mutated Collagen Promoter Display Normal Response During Bleomycin-Induced Fibrosis and Possess Neurological Abnormalities," Journal of Cellular Biochemistry, Vol. 77, pp. 135-148, 2000.					
	38	Hayashi et al., "Chronological Changes of Cerebral Ventricular Size in a Transgenic Model of Hydrocephalus," Pediatric Neurosurgery, Vol. 33, No. 4, pp. 182-187, 2000.					
EXAMINER					DATE CONSIDERED		
Examiner: Initial if citation considered, whether or not citation is in conformance with M.P.E.P. 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.							

Date: November 22, 2006

Form PTO-1449 (REV. 1/06)		US Dept. of Commerce PATENT & TRADEMARK OFFICE		ATTY DOCKET NO. 128045		APPLICATION NO. 10/579,297	
INFORMATION DISCLOSURE STATEMENT  (Use several sheets if necessary)				APPLICANTS Tsuyoshi TADA et al.			
				FILING DATE May 15, 2006			
U.S. PATENT DOCUMENTS							
Examiner Initials	Cite No.	Document Number	Date	Name			
FOREIGN PATENT DOCUMENTS							
Examiner Initials	Cite No.	Document Number	Date	Country	With English Abstract	With English Translation	
OTHER DOCUMENTS							
Examiner Initials	Cite No.	(Including Author, Title, Date, Pertinent Pages, etc.)					
	39	Morris, "Spatial Localization Does Not Require the Presence of Local Cues," Learning and Motivation, Vol. 12, pp. 239-260, 1981.					
	40	Sarnyai et al., "Impaired hippocampal-dependent learning and functional abnormalities in the hippocampus in mice lacking serotonin <sub>1A</sub> receptors," PNAS, Vol. 97, No. 26, pp. 14731-14736, December 19, 2000.					
	41	Cruz et al., "Observations on the use of medetomidine/ketamine and its reversal with atipamezole for chemical restraint in the mouse," Laboratory Animals, Vol. 32, No. 1, pp. 18-22, June 9, 1997.					
	42	Kern et al., "Concentrations of Hepatocyte Growth Factor in Cerebrospinal Fluid Under Normal and Different Pathological Conditions," Cytokine, Vol. 14, No. 3, pp. 170-176, May 7, 2001.					
	43	Weller et al., "Pathways of Fluid Drainage from the Brain - Morphological Aspects and Immunological Significance in Rat and Man," Brain Pathology, Vol. 2, pp. 277-284, 1992.					
	44	Kida et al., "CSF drains directly from the subarachnoid space into nasal lymphatics in the rat. Anatomy, histology and immunological significance," Neuropathology and Applied Neurobiology, Vol. 19, pp. 480-488, 1993.					
	45	Moinuddin et al., "Study of cerebrospinal fluid flow dynamics in TGF- $\beta$ 1 induced chronic hydrocephalic mice," Neurological Research, Vol. 22, pp. 215-222, March 2000.					
	46	Nitta et al., "Ultramicroscopic Structures of the Leptomeninx of Mice with Communicating Hydrocephalus Induced by Human Recombinant Transforming Growth Factor- $\beta$ 1," Neurol Med Chir (Tokyo), Vol. 38, pp. 819-825, 1998.					
EXAMINER					DATE CONSIDERED		
Examiner: Initial if citation considered, whether or not citation is in conformance with M.P.E.P. 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.							

Date: November 22, 2006

Form PTO-1449 (REV. 1/06)		US Dept. of Commerce PATENT & TRADEMARK OFFICE		ATTY DOCKET NO. 128045		APPLICATION NO. 10/579,297	
INFORMATION DISCLOSURE STATEMENT  (Use several sheets if necessary)				APPLICANTS Tsuyoshi TADA et al.			
				FILING DATE May 15, 2006			
U.S. PATENT DOCUMENTS							
Examiner Initials	Cite No.	Document Number	Date	Name			
FOREIGN PATENT DOCUMENTS							
Examiner Initials	Cite No.	Document Number	Date	Country	With English Abstract	With English Translation	
OTHER DOCUMENTS							
Examiner Initials	Cite No.	(Including Author, Title, Date, Pertinent Pages, etc.)					
	47	Taniyama et al., "Potential Contribution of a Novel Antifibrotic Factor, Hepatocyte Growth Factor, to Prevention of Myocardial Fibrosis by Angiotensin II Blockade in Cardiomyopathic Hamsters," Circulation, 2000, Vol. 102, pp. 246-252, <a href="http://circ.ahajournals.org/cgi/content/full/102/2/246">http://circ.ahajournals.org/cgi/content/full/102/2/246</a> , 01/31/06.					
	48	Adams et al., "Symptomatic Occult Hydrocephalus with 'Normal' Cerebrospinal-Fluid Pressure," The New England Journal of Medicine, Vol. 273, No. 3, pp. 117-126, July 15, 1965.					
	49	Tada et al., "Induction of communicating hydrocephalus in mice by intrathecal injection of human recombinant transforming growth factor- $\beta$ 1," Journal of Neuroimmunology, Vol. 50, pp. 153-158, 1994.					
	50	Kitazawa et al., "Elevation of Transforming Growth Factor- $\beta$ 1 Level in Cerebrospinal Fluid of Patients With Communicating Hydrocephalus After Subarachnoid Hemorrhage," Stroke, Vol. 25, No. 7, pp. 1400-1404, 1994.					
	51	Sajanti et al., "Transient increase in procollagen propeptides in the CSF after subarachnoid hemorrhage," Neurology, Vol. 55, pp. 359-363, 2000.					
	52	Miyazawa et al., "Protection of Hippocampal Neurons From Ischemia-Induced Delayed Neuronal Death by Hepatocyte Growth Factor: A Novel Neurotrophic Factor," Journal of Cerebral Blood Flow and Metabolism, Vol. 18, No. 4, pp. 345-348.					
EXAMINER					DATE CONSIDERED		
Examiner: Initial if citation considered, whether or not citation is in conformance with M.P.E.P. 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.							

Date: November 22, 2006